



DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances Registration: Catalent Pharma Solutions, LLC

[Docket No. DEA-392]

ACTION: Notice of registration.

SUMMARY: Catalent Pharma Solutions, LLC applied to be registered as an importer of a certain basic class of controlled substance. The Drug Enforcement Administration (DEA) grants Catalent Pharma Solutions, LLC registration as an importer of this controlled substance.

SUPPLEMENTARY INFORMATION:

By notice dated August 21, 2015, and published in the *Federal Register* on August 31, 2015, 80 FR 52510, Catalent Pharma Solutions, LLC, 3031 Red Lion Road, Philadelphia, Pennsylvania 19114 applied to be registered as an importer of a certain basic class of controlled substance. No comments or objections were submitted for this notice.

The DEA has considered the factors in 21 U.S.C. 823, 952(a) and 958(a) and determined that the registration of Catalent Pharma Solutions, LLC to import the basic class of controlled substance is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. The DEA investigated the company's maintenance of effective controls against diversion by inspecting and testing the company's physical security systems, verifying the company's compliance with state and local laws, and reviewing the company's background and history.

Therefore, pursuant to 21 U.S.C. 952(a) and 958(a), and in accordance with 21 CFR 1301.34, the above-named company is granted registration as an importer of hydromorphone (9150), a basic class of controlled substance listed in schedule II.

The company plans to import the above listed controlled substance for a clinical trial study. Approval of permit applications will occur only when the registrant's business activity is consistent with what is authorized under to 21 U.S.C. 952(a)(2). Authorization will not extend to the import of FDA approved or non-approved finished dosage forms for commercial sale.

Dated: February 10, 2016

Louis J. Milione,
Deputy Assistant Administrator.